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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,428	12/15/2003	Alfred J. Moo-Young	CBR 3.0-017 CONT	3967
530	7590	10/25/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			SHARAREH, SHAHNAME J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,428	MOO-YOUNG ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 3-22 is/are rejected.
- 7) Claim(s) 2 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/15/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 11, 2005 has been entered.

Claims 1-22 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1, 3-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardin et al US Patent 5,342,834 in view of Reed et al WO 97/29735.

The instant claims 1 and dependent claims thereof are directed to transdermal dosage forms of any non- 5α reducible, 7α modified androgen in therapeutically effective amount within a transdermal carrier wherein the dosage form provides a flux higher than testosterone in similar formulation and providing a rate of delivery between 400 to 1600 micrograms over 24 hour period.

Bardin discloses methods of delivering various androgens such as non- 5α reducible such as 7α derivatives of androgen (see col 2, lines 41-55). Bardin then claims delivery of such compounds transdermally in an amount of from 5 to 10 $\mu\text{g}/\text{kg}$ of body weight, which falls within the scope of the instantly recited concentrations.

Accordingly, Bardin teaches the limitations of claims 1 and 17.

Reed is used to show that such androgen as described by Bardin may be prepared in any form of transdermal delivery system in a form of emulsion, gel, aerosol , cream or lotion and even patches as articulated in various US Patents (see abstract, page 7, lines 5-25). In fact, Reed exemplifies various androgens and recites 7α

derivatives of androgen as suitable candidates for his drug delivery system (see page 11, lines 10-19).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to prepare the 7α derivatives of androgens of Bardin in a transdermal delivery systems as described by Reed and optimize suitable concentrations of the androgen of interest by routine experimentation., because as suggested by Bardin himself, such compounds can be administered transdermally to provide their systemic benefits.

One of ordinary skill in the art would have had a reasonable expectation of success in making a transdermal formulation of Bardin's androgens because as described by Bardin, such compounds are expected to provide clinical benefits when administered transdermally.

Allowable Subject Matter

3. Claim 2 is allowed. Applicant has provided evidence of unexpected results within the scope of claim 2. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

4. Applicant's arguments filed on July 11, 2005 have been fully considered and are found partially persuasive. Even though the arguments are moot in view of new ground of rejection. Examiner takes this opportunity to address Applicant's concerns. Applicants' arguments are essentially in two folds.

5. First, Applicant relying on the Declarations filed by Dr. Tsong under 37 CFR 1.132 filed July 11, 2005 ("Tsong's Declaration") argues that the claimed invention offers unexpected results in direct comparison with transdermal compositions described in Herschler. Such lines of arguments have been found persuasive. In fact, in view of the presented data, the rejection over Herschler has been withdrawn. More specifically claim 2 is declared allowable, because the data is commensurate with the scope of this claim and clearly establishes an unexpected higher serum concentration of the active agent.

However, in view of a newly presented art, a new ground of rejection is on now on record. The Tsong's Declaration does not apply to the new grounds of rejection because it is not commensurate with the scope of the rejected claims. See MPEP § 716.

6. Second, Applicant relying on the submitted Declaration of Dr. Bardin, the patentee of the '834 patent, argues that no useful transdermal product could have been produced because difference in a transdermal product and intramuscular or subcutaneous product of the claimed testosterone derivatives were legion. (see page 9 of the Response at the last paragraph). Applicant further argues that Dr. Bardin had no knowledge at the time that the claimed androgen would require a specific flux rate to provide specific serum blood levels. (see Remarks at page 10). These lines of reasoning appear to challenge the enablement requirement of the primary reference, the Bardin Patent.

7. In response, Examiner does not find the second line of arguments persuasive.

As the initial matter, Dr. Bardin's statements are not commensurate with the scope of the claims because none of the rejected claims is directed to a transdermal formulations of 7- α methyl 19 nortestosterone having a specific flux rate. Moreover, Dr. Bardin at col 1, line 55-59 of his patent states that "testosterone in skin is converted to 5- α dihydrotestastrone (DHT)," which can provide the androgenic action when in vivo. Therefore, there is at least some degree of interest to prepare topical androgenic formulations at the time of filing of Bardin's patent. Such interest amounts to a reasonable degree of motivation in the art to prepare topical androgenic composition.

8. Finally, it has been a long standing practice in the field of Patent Law that a prior art reference must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Samour*, 197 USPQ 1, 3-4 (CCPA 1978). Furthermore, " a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103." *Symbol Technologies, Inc. V. Opticon Inc.*, 935 F2d 1569, 1578 (Fed Cir. 1991). Thus, a non-enabling disclosure can act as prior art under § 103 for what it discloses and teaches, and therefore can be combined with other reference to render a claim obvious.

9. Here, even if allegedly Bardin's disclosure fail to appreciate the flux rate, there was ample understanding in the art how to prepare topical androgenic compositions, and as evidenced by Reed in WO 97/29735. The ordinary skill in the art viewing both cited references would have had a understanding and motivation as to form a topical formulation containing 7- α alky derivatives of testosterone.

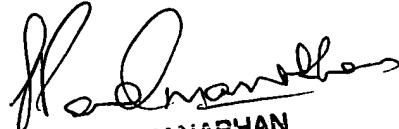
Conclusion

10. Claim 2 is allowable. All other claims stand rejected. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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